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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,711	02/17/2006	Kengo Akimoto	47231-5005	3090
55694 7590 03/27/2009 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER CARR, DEBORAH D	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 03/27/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/550,711

**Applicant(s)**

AKIMOTO ET AL.

**Examiner**

DEBORAH D. CARR

**Art Unit**

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-2, 11- 23, 32-44, 46-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 11- 23, 32-44, 46-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/08.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 4 April 2008 have been fully considered but they are not persuasive. The rejections of record are maintained for the reasons below.
2. Upon further consideration, a new rejection under 35 USC§112 is being made over the claims, see below.

### *(Old) Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 11- 23, 32-44, 46-49 rejected under 35 U.S.C. 102(b) as being anticipated by JP 2002-180082 or WO 02/06505 or Kawashima et al. or Namal et al. or Yoshida et al. or under 35 U.S.C. 102(a) as being anticipated by WO 03/004667.

### **Applicant argues the following:**

- 4.1 JP 2002-180082 [hereinafter the '082 application]

The '082 application describes the productions of a structural triglyceride having  $\omega$ 3-polyunsaturated fatty acid at position 2, and having middle chain fatty acids at positions 1 and 3, and the use thereof for treatment of some diseases or symptoms. However, the '082 application does not describe the triglycerides recited in the amended claims. Thus, the '082

application does not teach or suggest all the elements of the claims as amended. Accordingly, the rejection can be withdrawn in view of this reference.

4.2 Kawashima et al., JAOCS (2001)

Kawashima describes an enzymatic process for production of a structural lipid having  $\omega$ 3-polyunsaturated fatty acid at position 2 and having middle chain fatty acids at positions 1 and 3. The polyunsaturated fatty acids are docosahexanoic acid and eicosapentaenoic acid from fish oil and microbial produced arachidonic acid. Kawashima does not describe the triglycerides recited in the amended claims. Thus, Kawashima application does not teach or suggest all the elements of the claims as amended. Accordingly, the rejection can be withdrawn in view of Kawashima.

4.3 Sananayake et al., Lipids (2002)

All Sananayake describes is transesterification of oils such as borage oil, evening primrose oil, etc. so as to change positions of fatty acids on glyceride. The reference is thus irrelevant to the claims as amended. The rejection of the claims over this reference can also be withdrawn.

4.4 Yoshida et al., J. Nutr. Sci. Vitaminol. (1999)

Yoshida only describes that in natural seal oil, docosahexanoic acid and eicosapentaenoic acid are mainly positioned in triglyceride and are mainly positioned on position 2 in fish oil. Yoshida does not teach or suggest the presently claimed triglycerides. Accordingly, the rejection of the claims over this reference can also be withdrawn.

4.5 WO 02/06505

The PCT application describes a process for producing a structural lipid having polyunsaturated fatty acids (docosahexanoic acid, eicosapentaenoic acid, arachidonic acid) on position 2 and middle chain fatty acids on positions 1 and 3. The PCT application therefore does not teach or suggest the triglycerides of the amended claims. Thus, the rejection of the claims over this reference can be withdrawn.

4.6 WO 03/04667

This PCT application describes a process for producing a structural lipid having  $\omega$ 6-polyunsaturated fatty acid (ARA or DGLA) at position 2 and middle chain fatty acids on positions 1 and 3. This PCT application does not teach the triglycerides recited in the amended claims. Thus, the PCT application does not teach or suggest the amended claims. The rejection of the claims over this reference can also be withdrawn. Therefore, none of the references teach or suggest all the limitations of the claims as amended. Accordingly, the rejection under § 102(a) or (b) over these references can be withdrawn, and the claims allowed.

**Examiner's Response**

As seen supra, applicant concurs with the examiner it stating that the references teach omega fatty acids in the sn2 position. However, it is argued that the claims as amended are not anticipated by these references.

Claims 1 & 22 have been amended to list specific omega 3 & omega 6 fatty acids and recites omega 9 fatty acids broadly applicable for the sn2 position. Both of these claims state that the lipid-improving agent can contain one or more triglycerides with the required omega PUFA in the sn2 position. Since there are no limitations placed on the sn1 & sn3 positions and these references teach the required sn2 position, they still render the instant invention as claimed anticipated.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 11-21, 43, 46-49 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 11-21, 43, 46-48 recite the limitation "lipid-improving agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 from which these claims depend from read on a "liquid-improving agent" not a "lipid-improving agent". Based on this, claims 2, 11-21, 43, 46-48 lacks antecedent basis.

Claims 43, 46-48 additionally lack antecedent basis in regard to the term "composition" found in line 1 of the claim. There is no mention of a "composition" in claim 1 just a "lipid-improving agent", thereby rendering it indefinite for lacking antecedent basis.

Claims 18-21, 39-42 additionally lack antecedent basis regarding the function of the lipid-improving agent. As written on page 4 of the specification, the lipid-improving agent enhances the expression of hepatic PPAR $\alpha$  which is a transcription factor of an intranuclear receptor type and/or related gene and suppresses the expression of PPAR $\alpha$  of fat tissues and/or related gene. This being its inherent characteristics thereby lacks antecedent basis as cited in these claims.

Claims 12-13, 33-34, 47 are rendered indefinite by not containing proper Markush language. Claim terminology needs to be standardized in claim(s) 12-13, 33-34, 47. The language should be amended to read "selected from a group consisting of" so that standard Markush terminology is used.

#### ***Double Patenting***

5. Claim 44 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-25 of copending Application No. 10/485,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications embrace a food composition wherein the sn2 is occupied by an omega 6 PUFA and the sn1 & sn3 positions with a saturated FA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/  
Primary Examiner  
Art Unit 1621

Ddc

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Art Unit: 1621

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/Deborah D Carr/  
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